

REMARKS

Claims 1, 7-8, 11 and 27 stand rejected under Section 103 as unpatentable over Japanese Patent No. 2000-095663 (published March 4, 2000) (“Kondo”) in view of Rita Elkins, HAWAIIAN NONI (1998)(“Elkins”). Claims 11-12 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo in view of Elkins and U.S. Patent No. 5,503,825 (issued April 2, 1995)(“Lane”). Claims 1, 7-8, 11, and 27 stand rejected under Section 103 as being unpatentable over the Noni-now.com advertisements (<http://www.noni-now.com>)(“Advertisements”) in view of Kondo.

Claim Rejections under 35 U.S.C. § 103.

An invention is unpatentable under 35 U.S.C. § 103(a) (“Section 103”) “if the differences between the subject matter sought to be patented over the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.”

To establish a *prima facie* case of obviousness, three criteria must be met. “First, there must be some suggestion or motivation . . . to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

M.P.E.P. § 2142.

“Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.” *In re John R. Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992). Any such suggestion must be “found in the prior art, and not based on applicant’s disclosure.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Indeed, “[t]he mere fact that the prior art may be modified in the manner suggested

by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” M.P.E.P. § 2142.

A “clear and particular” showing of the suggestion to combine is required to support an obviousness rejection under Section 103. *Id.* For the reasons set forth below, Applicant submits that the relevant prior art fails both to teach or suggest all the claim limitations, and to clearly and particularly suggest the combination indicated by the Examiner; thus, Applicant’s claims are not obvious in view of the prior art references.

For the purposes of analysis, important elements of claim 1 have been designated with square brackets below. The analysis of prior art, which follows, refers to elements of claim 1 by the numbers designated inside square brackets.

1. (previously presented) A lip treatment comprising:

a composition for [1] topical application to provide [2] lip care, wherein the composition includes:

[3] *Morinda citrifolia* seed oil present in an amount [4] between about 0.1-20 percent by weight;

[5] *Morinda citrifolia* fruit juice present in an amount [6] between about 0.1-50 percent by weight; and

[7] at least one of:

- (i) linoleic acid; and
- (ii) xeronine.

1. Kondo in view of Elkins

Claims 1, 7-8, 11 and 27 stand rejected under Section 103 as unpatentable over Japanese Patent No. 2000-095663 (“Kondo”) in view of Elkins. The combination of Kondo and Elkins does not “teach or suggest all the claim limitations” of the present invention. M.P.E.P. § 2142. Specifically, the combination of Kondo and Elkins fails to teach the second, third, fourth, fifth and sixth elements of claim 1. The combination of Kondo and Elkins does not teach lip care, or the presence of *Morinda citrifolia* seed oil in combination with specific quantities of *Morinda citrifolia* juice. Kondo teaches *Morinda citrifolia* extract not *Morinda citrifolia* juice and not *Morinda citrifolia* seed oil. Kondo specifically indicates that “extracts [are] selected from ... plants [including]... *Morinda citrifolia* L ...” Consequently, Kondo does not teach the specific combination of *Morinda citrifolia* seed oil and fruit juice. In fact, Kondo teaches away from using *Morinda citrifolia* as claimed in the present invention. Kondo indicates that vegetable or fruit products alone fail to be effective treatment. Kondo, page 2 paragraph 4. Particularly, Kondo indicates that the antibacterial effects of vegetable extracts alone have a low effect. The present invention claims a composition for lip care, which may consist almost entirely of *Morinda citrifolia*. Thus, Kondo teaches away from using *Morinda citrifolia* as claimed in the present invention.

Further, Kondo teaches the use of vegetable or fruit extracts to inhibit melanin (to promote white skin), as astringents, (which would dry the skin) for removing the natural oils and sebum, as an antioxidant and as an antibacterial agent. First, lips do not produce melanin like skin. Thus, one skilled in the art would recognize that Kondo’s method for skin whitening is inapplicable to lips. Second, astringent, causes dry skin by removing excess oils and sebum. The drying effects of an astringent would have an undesirable effect on lips which do not

produce oil or sebum. Lips would benefit from the use of an antioxidant, but it is unclear that the extracts taught by Kondo would provide lip care. Thus, the disclosure in Kondo only teaches or suggests claim limitation 1, which is a “topical application.”

Elkins fails to “teach or suggest all the claim limitations” of the present invention.

M.P.E.P. § 2142. Elkins teaches the use of parts of the noni plant. However, Elkins does not disclose the use of seeds. In particular, Elkins does not disclose the use *Morinda citrifolia* seed oil which is claimed as the third element in the first claim of the present invention. Further, Elkins does not suggest combining *Morinda citrifolia* juice with seed oil or with other elements of the *Morinda citrifolia* plant. The Examiner suggests that Elkins on pages 9-11 teaches the use of the fruit, seeds, bark, leaves, and the flowers of *Morinda citrifolia*. However, pages 9-11 of the Elkins disclose the use of *Morinda citrifolia* leaves, flowers, fruit, roots and root bark, but not seeds. The Examiner suggests that page 30 of Elkins provides a suggestion to use noni as a skin healing agent due to the presence of proxeronine. Elkins discloses at various places including page 19, 20 and 30 traditional uses of noni. Specifically, Elkins discloses uses for noni including: delayed menstruation, antiphlastic activity, respiratory ailments, diarrhea, to kill intestinal parasites, stomach ailments, diseased gums, tuberculoses, fever, eye complaints, inflamed gums, sore throats, boils, swelling, arthritic joints and ringworm. Elkins, 19-20.

Further on page 30, Elkins indicates that noni is used as a skin healing agent. In particular, Elkins indicates that noni is used as a poultice for wounds, burns and bruises. The content of the Elkin’s discussion focuses on the benefits of using a noni poultice for quickly removing dead tissue from burns. Thus, Elkins teaches the removal of dead skin from burns not the topical application of oil from seeds of *Morinda citrifolia* for lip care. Further, Elkins does not disclose

the combination of *Morinda citrifolia* seed oil in *Morinda citrifolia* juice in specific quantities as claimed in the present invention.

Thus, the combination of Kondo in view of Elkins fails to teach or suggest the combination of limitations claimed in the present invention.

2. Kondo in view of Elkins and Lane

Claims 11-12 and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kondo in view of Elkins and Lane.

As indicate above, the combination of Kondo and Elkins fails to teach or suggest the claim limitation of the present invention. The addition of Lane as prior art also fails to teach or suggest the claim limitations of the present invention. Lane teaches a topical a lip balm containing aloe vera, salt and a pharmaceutically accepted topical medium. Lane, like Kondo and Elkins fails to suggest or teach the use of seed oil from *Morinda citrifolia* in combination with fruit juice from *Morinda citrifolia* in specific concentrations. Further, there is no suggestion in Lane for the use of *Morinda citrifolia* products. “Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absence some teaching or suggestion supporting a combination.” In re John R. Fritch, 972 F2d 1260, 1266 (Fed. Cir. 1992). Thus, although Lane discloses the use of a lip balm, there is no suggestion in Lane to use *Morinda citrifolia* as a lip treatment product. Because the combination of Kondo, Elkins and Lane fails to disclose or suggest all the limitations of the present invention, the present invention is not anticipated by Kondo in view of Elkins and Lane.

3. *Noni-now.com* in view of *Kondo*

Claims 1, 7-8, 11, and 27 stand rejected under Section 103 as being unpatentable over the *Noni-now.com* advertisements (<http://www.noni-now.com>)(the “Advertisements”) in view of *Kondo*.

The Advertisements depict an SPF lip balm containing noni (the “Lip Balm Product”), neither this product nor the composition disclosed in *Kondo* anticipates or renders obvious the present invention as neither reference discloses or suggests a lip treatment comprising “*Morinda citrifolia* seed oil [and] *Morinda citrifolia* fruit juice” as recited in independent claim 1 of the present application.

Indeed, the Advertisement features only a lip balm that “gives you the benefits of noni and protection from the sun.” The Advertisement fails to disclose or suggest any particular components of the advertised lip balm.

Similarly, *Kondo*, as previously discussed, does not suggest or teach the combination of *Morinda citrifolia* seed oil present in a specific amount in combination with *Morinda citrifolia* juice present in a specified amount. *Kondo* does not teach or suggest a lip balm containing either *Morinda citrifolia* seed oil or *Morinda citrifolia* fruit juice. Consequently, the combination of *Kondo* and the Advertisement fail to teach or suggest a lip balm containing *Morinda citrifolia* seed oil and *Morinda citrifolia* fruit juice at specified concentrations.

Moreover, the Tahitian Noni® Skin Supplement and Tahitian Trim® Plan 40 Body Balance Cream (collectively, the “Skin Products”) also do not render the present invention obvious alone or in combination with the advertised Lip Balm Product or *Kondo* since the Skin Products are formulated to moisturize and protect the skin generally, and do not mention or suggest beneficial application to the lips. As epidermal skin generally is drastically

physiologically distinct from the physiology of the lips, disclosure of the beneficial effects of noni oil and juice as components of the Skin Products does not inherently suggest the same beneficial effects as applied to the lips.

Indeed, “lips aren’t really skin,” (see www.lipandlips.com/Lips_pages/lips_anatomy.htm, visited January 22, 2004), and thus skin products designed for application to the average epidermal surface are generally not well suited for the lips. Specifically, unlike the rest of our skin, lips aren’t protected by a densely packed layer of tissues known as cornified tissue. Lips also lack oil glands, have less pigment than skin, and cannot grow hair. Nerve endings in the lips are very close to the surface, unlike epidermal nerve endings generally, which makes the lips appear pink or red.

As the combined references fail to mention or suggest a composition for topical application to provide lip care comprising *Morinda citrifolia* seed oil and *Morinda citrifolia* fruit juice, one skilled in the art would not be motivated to combine the references as the Examiner suggests. The Examiner’s rejection thus constitutes an improper hindsight based rejection lacking support in fact as of the present date of invention.

Applicant respectfully submits that the inability of the combined references cited by the Examiner to produce the invention as claimed, and the lack of any suggestion or motivation to modify such art to produce Applicant’s invention as claimed renders the present invention non-obvious in view of such references.

As claims 7-8, 11-12, 22 and 27 add further limitations to otherwise allowable subject matter, such claims are also not rendered obvious by the cited references.

Accordingly, Applicant respectfully requests withdrawal of the rejections of claims 1, 7-8, 11-12, 22 and 27 as obvious in view of the cited references under Section 103.

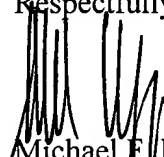
CONCLUSION

Based on the foregoing, Applicant believes that the claims of the present invention are in condition for allowance and respectfully requests the same.

Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to initiate a telephone interview with undersigned counsel.

DATED this 20 day of August, 2004.

Respectfully submitted,



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